K062752

Appendix A
510(k) Summary of
Safety and Effectiveness

DEC - 7 2006

Submitted by	Kirk P. Seward, Ph.D President and Chief Technology Officer Mercator MedSystems, Inc. 3077 Teagarden Street San Leandro, CA 94577 Telephone: 510 614-4550 Facsimile: 510 667-0435
Contact Person	Same as above
Date Summary Prepared	August 15, 2006
Trade Name	Mercator MicroSyringe II Infusion Catheter
Common Name	Continuous Flush Infusion Catheter (per 21 CFR 870.1210)
Performance Standards	Not promulgated for Continuous Flush Infusion Catheters
Classification	KRA/Class II
Panel	Cardiovascular

Predicate Devices

Mercator MicroSyringe Infusion Catheter Manufactured by Mercator MedSystems, Inc.	K040139
Dispatch Coronary Infusion Catheter Manufactured by SCIMED® Life Systems, Inc.	K932616
Selective Infusion II Catheter Manufactured by ACS®/Guidant, Inc.	K914751
Isolate Infusion Catheter System Manufactured by Lake Region, Inc.	K913517

Device Description

The Mercator MicroSyringe II is a wire-guided endovascular catheter that consists of a perpendicular microneedle delivery port, which is sheathed by and contained within a semi-rigid polymer balloon actuator with an integrated compliant low-pressure forcing balloon opposite the microneedle. The device is advanced over a 0.014" guidewire, using a single operator method, into the treatment vessel and hydraulically actuated to move the needle delivery port into the vessel in order to deliver substances to vascular structures.

Intended Use

In selective areas of peripheral and coronary vessels, the MicroSyringe II Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents that are indicated for delivery into the vessel wall or perivascular area. The MicroSyringe II Infusion Catheter is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

Technological Characteristics
All materials used in the manufacture of the MicroSyringe II are suitable for this use and have been used in several previously cleared products.

Testing
Testing of mechanical and fluid delivery performance, biocompatibility, sterilization validation, and in-vivo safety were conducted to ensure the MicroSyringe II met all of its pre-determined specifications.

All components, subassemblies and/or full devices met the required specifications for the tests. The results of these tests demonstrated that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mercator MedSystems, Inc.
c/o Kirk P. Seward, Ph.D.
President and Chief Technology Officer
3077 Teagarden Street
San Leandro, CA 94577

DEC - 7 2006

Re: K062752
Mercator MicroSyringe II Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Infusion Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: November 20, 2006
Received: December 1, 2006

Dear Dr. Seward:

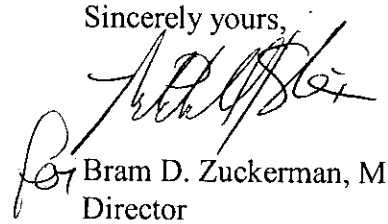
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062752

Device Name: Mercator MedSystems MicroSyringe II Infusion Catheter

Indications For Use:

In selective areas of peripheral and coronary vessels, the MicroSyringe II Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents that are indicated for delivery into the vessel wall or perivascular area. The MicroSyringe II Infusion Catheter is also intended for the infusion of diagnostic and therapeutic agents intraluminally.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062752